SOLICITOR

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AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	U.S. PATENT & TRADEMARK OFFICE

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court TRENTON on the following ☑ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
07-2895 (GEB)	6/22/2007	TRENTON

PLAINTIFF	DEFENDANT
TEVA PHARMACEUTICAL INDUSTRIES LTD. et al	WATSON PHARMACEUTICALS, INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	6,699,997		SEE ATTACHED COMPLAINT
2	6,710,184		
3	7,056,942		
4	7,126,008		
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
WILLIAM T. WALSH, CLERK	Kitty Herndon	6/22/2007

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

6. Awarding Plaintiffs such other relief that the Court deems proper, just and equitable.

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: June 21, 2007

/s/ Michael E. Patunas
Allyn Z. Lite
Michael E. Patunas
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
(973) 623-3000

Attorneys for Plaintiffs Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs, by their attorneys, hereby certify that the matter in controversy is also the subject of the following actions:

Caption	Docket No.Court
Teva Pharmaceutical Industries Ltd., et al. v. Ranbaxy Laboratories, Ltd., et al.	Filed on 6/21/07 D.N.J.
Teva Pharmaceutical Industries Ltd., et al. v. Dr. Reddy's Laboratories Inc., et al	Filed on 6/21/07 D.N.J.

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: June 21, 2007

/s/ Michael E. Patunas
Michael E. Patunas

LITE DEPALMA GREENBERG & RIVAS, LLC
Allyn Z. Lite
Michael E. Patunas
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
(973) 623-3000
Attorneys for Plaintiffs Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,	:	
Plaintiffs	:	Civil Action No. 07-2895 (GEB)
v.	:	
WATSON PHARMACEUTICALS, INC.,	:	
Defendant.	:	

COMPLAINT FOR DECLARATORY JUDGMENT

For their Complaint against Defendant Watson Pharmaceuticals, Inc. ("Defendant"), Plaintiffs Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA"; collectively, "Plaintiffs") allege as to their own acts, and on information and belief as to the acts of others, as follows:

THE PARTIES

1. Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

2. Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly-owned subsidiary of Teva Ltd.

3. On information and belief, Defendant is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California. On further information and belief, Defendant is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey. On further information and belief, Defendant is registered to do business in the state of New Jersey and maintains a business address at 200 South Orange Avenue, Livingston, New Jersey.

NATURE OF THE ACTION

4. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking injunctive relief under 35 U.S.C. §§ 281-283.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

7. This Court has personal jurisdiction over Defendant because of, *inter alia*, Defendant's systematic, purposeful and continuous contacts with this District, registration to do business in this District, and maintenance of a business address in this District.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

FACTUAL BACKGROUND

The Patents in Suit

9. Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,699,997 ("the '997 Patent"), 6,710,184 ("the '184 Patent"), 7,056,942 ("the '942 Patent"), and 7,126,008 ("the '008 Patent"; collectively, "the patents in suit") relating to, *inter alia*, various forms of a chemical compound known as carvedilol and processes for preparing various forms of carvedilol. One polymorphic form of carvedilol is known as "Form II."

10. The '997 Patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on March 2, 2004 for an invention entitled "Carvedilol." A copy of the '997 Patent is attached as Exhibit A.

11. The '008 Patent was duly and legally issued by the PTO on October 24, 2006 for an invention entitled "Carvedilol." A copy of the '008 Patent is attached as Exhibit B.

12. The '997 and '008 Patents claim processes for preparing carvedilol.

13. The '184 Patent was duly and legally issued by the PTO on March 23, 2004 for an invention entitled "Crystalline Solids of Carvedilol and Processes for Their Preparation." A copy of the '184 Patent is attached as Exhibit C.

14. The '184 Patent claims processes for preparing carvedilol Form II.

15. The '942 Patent was duly and legally issued by the PTO on June 6, 2006 for an invention entitled "Carvedilol." A copy of the '942 Patent is attached as Exhibit D.

16. The '942 Patent claims, *inter alia*, a hydrate form of carvedilol hydrochloride.

GlaxoSmithKline's Exclusivity

17. Carvedilol is a pharmaceutical compound used in the treatment of congestive heart failure. It is the active pharmaceutical ingredient ("API") in the product sold by GlaxoSmithKline ("GSK") under the trade name COREG®. COREG® is included in the United States Food and Drug Administration's ("FDA") list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs listed in the Orange Book may be used as the basis of a later applicant's Abbreviated New Drug Application to obtain approval of the applicant's generic drug product under 21 U.S.C. § 355(j).

18. The carvedilol compound is disclosed and claimed in U.S. Patent No. 4,503,067 ("the '067 Patent"), which is owned by GSK. The '067 Patent is listed in the FDA's Orange Book in association with COREG®. The '067 Patent expired on March 5, 2007.

19. Pursuant to 21 U.S.C. § 355a, GlaxoSmithKline was awarded a six-month period of pediatric exclusivity following the expiration of the '067 Patent. GlaxoSmithKline's pediatric exclusivity period extends from March 5, 2007 to September 5, 2007. Pursuant to this exclusivity, the FDA cannot grant final approval to any Abbreviated New Drug Application ("ANDA") holders for carvedilol during that period. The FDA may grant final approval to ANDA holders beginning immediately upon expiration of GSK's pediatric exclusivity period.

Defendant's Imminent Infringement of the Patents in Suit

20. On information and belief, Defendant submitted ANDA No. 77-474 to the FDA, requesting approval to market a generic version of COREG® in 3.125, 6.25, 12.5, and 25 mg dosage strengths.

21. Defendant has received tentative approval of its ANDA from the FDA. On information and belief, final approval of Defendant's ANDA is expected to be granted shortly after the expiration of GSK's pediatric exclusivity period on September 5, 2007. Once Defendant receives final approval of its ANDA, it will be able to market generic carvedilol tablets in the United States.

22. Under the Hatch-Waxman Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. ANDA holders may make the API themselves or, instead, may purchase the API from a supplier. When an ANDA holder intends to purchase API from a supplier to use in the proposed product, the ANDA holder may reference a Drug Master File ("DMF") submitted to the FDA by that supplier, instead of providing process information in the ANDA. Plaintiffs have been unable to obtain from a public source any information regarding whether Defendant will make or purchase the API to be used in its proposed products.

23. On information and belief, Defendant plans and intends to make carvedilol API or to purchase carvedilol API from a third party DMF holder, to use in the manufacture of its proposed generic carvedilol tablets ("Defendant's tablets").

24. On information and belief, Defendant plans and intends to engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic carvedilol tablets in the United States.

25. On information and belief, Defendant plans and intends to engage in the activities described in paragraph 24 immediately upon receiving final approval of its ANDA from the FDA and said approval will occur shortly after GSK's pediatric exclusivity period expires.

26. On information and belief, Defendant plans and intends to engage in the activities described in paragraph 24 prior to the expiration of the patents in suit.

27. On information and belief, Defendant's tablets will include carvedilol API that infringes or will infringe one or more claims of the patents in suit, and/or that is or will be made by a process that infringes one or more claims of the patents in suit. Accordingly, Defendant's plans and intentions to make and sell carvedilol tablets in the United States constitute imminent, threatened acts of infringement under 35 U.S.C. § 271, which give rise to an actual controversy over which the Court may exercise jurisdiction.

28. Plaintiffs have made a reasonable effort to determine the chemical composition of the carvedilol API to be used in Defendant's tablets, as well as the process by which the carvedilol API to be used in Defendant's tablets is or will be made. On May 10, 2007, Teva USA notified Defendant of the existence of the patents in suit and sought information allowing Plaintiffs to ascertain whether Defendant's tablets and/or the API to be used in Defendant's tablets fall within the scope of one or more of the patents in suit, and/or whether the API to be used in Defendant's tablets is made pursuant to a process that falls within the scope of one or more of the patents in suit. In particular, Teva USA requested a detailed description of all processes that will be used to manufacture Defendant's tablets, all processes that will be used to make the API to be used in Defendant's tablets, samples of Defendant's tablets, and samples of the API to be used in Defendant's tablets. Teva USA offered to enter into a confidentiality agreement to protect the confidentiality of any information disclosed by Defendant. Pursuant to this offer, Teva USA supplied a proposed confidentiality agreement to Defendant.

29. Defendant has not provided to Teva USA samples of Defendant's tablets or of the API to be used in Defendant's tablets, or the detailed information requested regarding the processes by which Defendant's tablets are manufactured or the API to be used in the tablets is made, despite Teva USA's offer of confidentiality. Further, Plaintiffs have been unable to obtain from a public source samples of Defendant's tablets or the API to be used in their manufacture.

30. Without the requested information, Plaintiffs are unable to determine whether Defendant's tablets, or the API to be used in Defendant's tablets, infringes one or more compounds claimed in the patents in suit, or whether the processes by which the API is made infringe one or more methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendant infringes each of the patents in suit unless and until Defendant provides samples of its tablets and samples of the API to be used in their manufacture and discloses to Plaintiffs the processes by which the tablets and API are made.

31. In the absence of a sufficient response from Defendant, Plaintiffs have no choice but to resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present the Court evidence that Defendant will infringe the patents in suit.

32. As a direct and proximate consequence of the planned and intended infringement by Defendant, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury for which they are entitled to relief.

COUNT I

Declaratory Judgment of Patent Infringement

33. Plaintiffs repeat and reallege Paragraphs 1 through 32 of the Complaint as if fully set forth herein.

34. On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendant of its carvedilol tablets pursuant to ANDA No. 77-474 will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Teva Ltd. and Teva USA respectfully request a judgment from the Court:

1. Declaring that Defendant will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271;

3. Declaring that Defendant's infringement will be willful and that this is an exceptional case under 35 U.S.C. § 285;

4. Permanently enjoining Defendant, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '997, '184, '942, and '008 Patents;

5. Awarding Plaintiffs their attorneys' fees, costs, and expenses; and